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EXAMINER	
CANELLA, KAREN A	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/776,250	BERD, DAVID	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 21-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) 21-56 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. After review and reconsideration, the finality of the Office action of April 9, 2003 is withdrawn.

2. Claims 13-20 have been canceled in the amendment filed June 9, 2003. Claims 21-56 are pending and under consideration.

3. Sections of Title 35, U.S. Code not found in this action, can be found in a previous action.

4. Claims 21-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) It is unclear how claim 24 further modifies claim 22. Claim 24 recites "in which the adjuvant is Bacille Calmette-Guerin". However, claim 22 specifies "free from any adjuvant".

(B) It is unclear how claim 54 further modifies claim 51. Claim 51 recites "free of any adjuvant". Claim 54 specifies wherein the adjuvant is selected from a group consisting of BCG, Q21 and detoxified endotoxin.

(C) Claims 21 and 51 are vague and indefinite because they lack a recitation of the timing of the administration of the second tumor cell composition. Because the timing of the induction dose and the immunomodulatory agent is specified, and because the timing of the second tumor cell composition is not specified, it is unclear if the second tumor cell composition is to follow the immunomodulatory composition, or if the second tumor cell composition can be administered at any time during the treatment.

(D) The recitation of "haptenized tumor cell or tumor cell extracts" in claim 23 is vague and indefinite in that it is unclear if "haptenized" refers to the tumor cell extract as well as the tumor cells. The recitation of "haptenized autologous tumor cell or tumor cell extract" in claim 23 is also unclear for the same reasoning as above. For purpose of examination, both alternatives will be considered.

(E) The recitation of "autologous tumor cell or tumor cell extract" in claim 21 is vague and indefinite in that it is unclear if "autologous" refers to the tumor cell extract as well as the tumor cells. For purpose of examination. Both alternatives will be considered.

(F) The recitation of "tumor cells or tumor cell extract(s) which corresponds to from about 2 X 105 to about 2.5 X 106 tumor cells" in claims 21 and 23 is vague and indefinite because it is unclear if the limitation of from about 2 X 105 to about 2.5 X 106 tumor cells free of any adjuvant" is to be applied to the "tumor cells" as well as the "tumor cell extracts. For purpose of examination, both alternatives will be considered.

(G) Claim 25 is vague and indefinite in the recitation of "tumor cells or tumor cell extract" in reference to claim 21 because it is unclear if the limitation of claim 25 is to be applied to section (a) or (b) or both sections (a) and (b) of claim 21.

(H) Claim 26 is vague and indefinite because it is unclear if applicant intends the mixture to comprise haptenized tumor cells and non-haptenized tumor cells or haptenized tumor cells and tumor cell extract, or if applicant intends to encompass a mixture of haptenized tumor cell extract and non-haptenized tumor cell extract.

(I) Claims 27, 30 and 31 are vague and indefinite because it is unclear if the limitation of claims 27, 30 and 31 are to be applied to section (a) or (b) or both sections (a) and (b) of claim 21, all of which specify tumor cells or tumor cell extracts.

(J) The recitation of "tumor cell equivalents" in claim35 lacks antecedent basis in claim 21.

(K) The recitation of "tumor cell equivalents" in claims 36 and 37, lacks antecedent basis in claim 31.

(L) It is unclear how claim 31 further limits claim 21 because tumor cell polypeptides would inherently be comprised with the tumor cell extracts of claim 21.

(M) It is unclear how claim 38 further modifies claim 21 because claim 21 specifies that the administration is free of adjuvant.

(N) Claim 46 is vague and indefinite in the recitation of "a second composition comprising an adjuvant and a tumor cell, which second composition contains from about 2 X 105 to about 2.5 X 106 tumor cell or tumor cell equivalents". It is unclear how the second composition comprising the tumor cell equivalent can meet the limitation of "comprising a tumor

cell" as stated in line 7. Claim 46 is also vague and indefinite in the recitation of "non-haptenized tumor cells...comprising tumor cells or cell equivalents....wherein the tumor cells or cell equivalents are conjugated to a hapten". It appears that the claim has several contradictory elements, such as requiring tumor cells, but incorporating language e of "cell equivalents", and requiring haptenized or non-haptenized tumor cells and then requiring that the tumor cells are conjugated to a hapten which would exclude the non-haptenized tumor cells.

(O) Claims 21, 23, 46, 51 and 55 are vague and indefinite in the recitation of "from about" and "to about". The specification states on page 6, lines 17-19, that the term "about" means within an acceptable standard error of the mean when considered by one of ordinary skill in the art. Thus, the term "about" is a term reliant on the judgment of "acceptable" by one of ordinary skill in the art. Because different practitioners of the art can judge different values to be "acceptable standard error", one of skill in the art would not be able to determine the metes and bounds of what applicant intends as the claim limitations. The M.P.E.P (2171) states that there are two separate requirements to satisfy 112, 2nd paragraph which are
(A) the claims must set forth the subject matter that applicants regard as their invention; and
(B) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

The M.P.E.P states that the first requirement is a subjective one because it is dependent on what the applicants for a patent regard as their invention. However, the M.P.E.P also states that the second requirement is an objective one because it is not dependent on the views of applicant or any particular individual, but is evaluated in the context of whether the claim is definite - i.e., whether the scope of the claim is clear to a hypothetical person possessing the ordinary level of skill in the pertinent art. A potential infringer could not determine the exact metes and bounds of the instant claims, because the definition of the term "about" leaves it to the discretion of one of skill in the art as to what constitutes an "acceptable" standard error.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 21 and 23-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. .

Claims 21 and 23-56 are method claims reliant on the identity of "an immunomodulatory agent that potentates protective anti-tumor immunity or inhibits immune suppression or both". Thus said claims encompass within the claimed method a genus of "immunomodulatory agents" having the ability to potentiate protective anti-tumor immunity, "immunomodulatory agents" having the ability to potentiate protective anti-tumor immunity and inhibit immune suppression, and "immunomodulatory agents" which inhibit immune suppression. The specification describes "cyclophosphamide" as an immunopotentiator which temporarily diminish down-regulation of anti-tumor response(s) and increases protective anti-tumor immunity. The specification describes "immunostimulants" such as endotoxin and endogenous agents, e.g., cytokines and lymphokines, including but not limited to IL-2, IL-4, INF-gamma., IL-12, and GM-CSF (page 24, lines 1-7), however the specification does not describe these compounds as potentiating protective anti-tumor immunity. The genus of immunomodulatory agents which potentiate protective anti-tumor immunity is limited only by functional attribute. It is noted that post-filing art has identified melphalan and adriamycin as cytotoxic drugs which have immunopotentiating effects when given "in the right way" (Berd, Vaccine, 2001, Vol. 19, pp. 2565-2570). The post filing reference provides no teachings regarding the dose of melphalan and adriamycin effective for the immunopotentiating effect versus a cytotoxic effect, nor dose the reference provide evidence that the timing the administration of melphalan or adriamycin in a vaccine regimen of hapten-modified melanoma vaccine would be the same as the timing of the administration of cyclophosphamide in the regimen of hapten-modified melanoma vaccine. The description of "cyclophosphamide" as the preferred immunomodulator of the invention fails to describe the genus of immunomodulators because said genus encompasses molecules which

have no structural relationship to cyclophosphamide, such as melphalan and adriamycin, and therefore would not be expected to be administered in the same dosage or with the same timing to have the same function as cyclophosphamide within the claimed method. One of skill in the art would reasonable conclude that applicant was not in possession of a genus of immunomodulators which potentiated anti-tumor immunity, or potentiated anti tumor immunity in addition to inhibiting immune suppression. It follows from this that applicant was not in possession of method claims reliant on said genus of immunomodulators.

7. Claims 21-56 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The factors to be considered in determining whether undue experimentation is required are summarized In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (Wands, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (Wands, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The instant claims are broadly drawn to a method for inducing an anti-tumor response in any patient. The claims encompass anti-tumor responses which are humoral, cellular, humoral and cellular and anti-tumor immune responses which are not effective to treat the tumor. The claims encompass the induction of said anti-tumor response for a multitude of cancers (for

example claim 32) using a multitude of haptens (claims 28 and 47). Claims 25-45 and 51-56 require the administration of the immunomodulatory agent four to seven days after the priming dose of tumor cells or tumor cell extracts, followed by a second composition comprising tumor cells or tumor cell extracts, however claims 46-50 do not require the immunomodulatory agent. (A)As drawn to the induction of an anti-tumor response that does not result in therapeutic efficacy when administered to a patient in need thereof.

The instant claims are drawn to the induction of a "anti-tumor response" in a mammalian patient suffering from a tumor. When given the broadest reasonable interpretation, the claims encompass the generation of an anti-tumor response which is not effective to cause tumor regression or prevent the progression of the tumor. It is well known in the art, that an anti-tumor immune response can be a humoral immune response but that a strong humoral immune response does not correlate with a demonstrable resistance to the tumor (Paul, Fundamental Immunology (text), 1993, pp. 1158, second column, lines 1-5 under the heading "Antibodies and B Cells"). The art teaches that in rare instances, an antibody can cause the regression of a tumor, but that in most cases a cell-mediated immune response is necessary (Hunter et al, WO 92/00101, page 2, lines 17-22). Thus, a humoral immune response would not be expected to cause tumor regression or prevent the progression of a tumor. Further, an anti-tumor immune response also encompasses the induction and/or proliferation of CD+4 suppressor T cells, which would be a negative anti-tumor response, nor expected to have a therapeutic effect. Further, it is well known in the art that the induction of CD+8 T-cells within a patient suffering from a cancer does not have a nexus with a cytolytic response against the cancer because it has been demonstrated that the presence of a CD+8 T cell within a patient that is cytolytic in vivo does not correlate with a cytolytic response in vivo (Yu and Resifo, Journal of Clinical Investigation, 2002, Vol. 110, pp. 289-294, especially page 292, first column, under the heading "Consistent increases in tumor-specific T cells without consistent clinical responses"). Thus, the induction of an anti-tumor response by means of inducing tumor-specific CTL in a patient does not have a nexus to a therapeutic regression of a tumor or the prevention of tumor progression. Therefore, one of skill in the art would be subject to undue experimentation in order to use the other types of anti-tumor immune response generated by the claimed methods, because not all immune responses cause a therapeutic response in a patient having a tumor.

(B) as drawn to methods which do not require the administration of CY at specific time after the priming dose and before the second dose.

Claims 46-50 does not require the administration of the immunomodulatory agent after the priming dose, but before the second dose of tumor cells or tumor cell extracts. Claims 55 and 56 include the administration of the second composition on the same day as the administration of the cyclophosphamide when cyclophosphamide is administered seven days after initiation of treatment. It is noted that the specification states on pages 31-32 (bridging sentence) that the timing of the priming induction dose several day prior to administration of a low-dose cyclophosphamide and not near or on the same day as CY apparently determines whether the subsequent course if DNP-modified vaccine results in tumor immunity or unresponsiveness. This finding is corroborated by the post filing art (Berd, Expert Review of Vaccines, 2004, Vol. 3, pp. 521-527, especially page 525 under the heading of "Importance of the DNP-vaccine dosage schedule"). The specification provides enablement for a method of inducing an anti-metastatic effect in patients suffering from melanoma, wherein the primary tumor had been removed from said patients (Example 3, page 29, lines 24-27 and page 30, lines 5-10). The specification teaches that "Protocol A" patients had a 5-year relapse free survival rate of 41% relative to Protocols B and C which varied from protocol A in the timing of the cyclophosphamide and second composition of tumor cells. Thus, it appears to be critical for tumor immunity that the cyclophosphamide be administered between four and 7 days after the priming dose of tumor cells or tumor cell extracts in order for efficacy to result, however, this limitation is not part of claims 46-50.

(C)As drawn to a therapeutic induction of an anti-tumor response in patients having metastatic lesions.

Claims 21-32, 34-47, 49-51 and 53-56 encompass methods of inducing anti-tumor responses in patients having metastatic disease to various organs. The specification specifically contemplates the treatment of liver metastases of colon tumors (page 9, lines 1-5). The art teaches (Berd, Seminars in Oncology, Dec 1998, Vol. 25, pp. 605-610) that the requirement for successful immunotherapy are an immunogenic tumor, intact cell-mediated immunity in the patient and low tumor burden (page 605, second column, first paragraph under the heading of "Principles of Immunotherapy"). The art further teaches that in patients with advanced

metastatic cancer, the total body tumor burden may be several orders of magnitude above the level of tumor burden which can be effectively treated by immunotherapy (ibid, page 606, first column, paragraph before the heading "Experimental Basis for Cancer Vaccine Therapy"). The post-filing date art (Berd, Vaccine, 2001, Vol. 19, pp. 2565-2570) teaches that tumor regression of metastatic lesions is uncommon despite the immune response induced at the metastatic sites by administration of autologous DNP-tumor compositions, but that only small lung metastases are likely to regress when given the DNP-haptenized melanoma composition (Berd, 2001, page 2568, second column, lines 1-6 under the heading "Anti-tumor responses"). It is noted that the post-filing art, termed this result as "peculiar". Thus, the treatment of metastatic disease, apart from the treatment of melanoma metastatic to the lung, is unpredictable. One of skill in the art would be subject to undue experimentation without reasonable expectation of success in order to treat the metastatic lesions in a patient by using the claimed method.

(D)As drawn to haptens which are not DNP.

Claims 21-28 and 30-56 encompass haptenized tumor cells in which the hapten is not DNP. The prior art teaches how to make a composition comprising autologous melanoma cells haptenized with DNP (Sato et al, Clinical Immunology and Immunopathology, 1995, Vol. 74, pp, 35-43), wherein administration of the haptenized preparation causes inflammation in tumor cells. The art teaches that the ability of hapten-conjugated cells to induce cell-mediated cytotoxicity is affected by the hapten linkage and that haptens which are coupled via an azo-linkage completely fail to generate cytotoxic cells (Hanas and Leskowitz, Cellular Immunology, 1980, Vol. 54, pp. 241-247, especially pages 246-247). The specification provides no guidance in how to prepare tumor cells or tumor cell extracts which have been "haptenized" with the multitude of haptens encompassed by the claims. It is noted that the specification contemplates diazonium salts and modification of aryl side chains, histidines and tryptophans (page 18, line 3 and lines 16-20) consistent with the negative teachings of Hanas and Leskowitz (ibid). The specification discusses neither the level of modification, or the chemical linkage. One of skill in the art would be required to determine for each of the haptens in claim 28 the optimum linkage means to the tumor cell, the optimum level of modification each different type of tumor cell requires and the optimum chemical conditions by which to achieve the desired modification by the desired linkage, and thus would be subject to undue experimentation in order to carry out the

broadly claimed method for all tumor types encompassed by the claims and all haptens encompassed by the claims.

(E) As drawn to the treatment of domestic pets and livestock

Claims 21-40, 42, 43, 45-56 encompass the treatment of a mammalian patient which is not a human patient. Claims 39 and 42 specify that the patient is a domestic pet or livestock. Further Srivastava et al (WO98/34641) teach that the amount of antigen required for activation of antigen-presenting cells within human skin via and intradermal injection is smaller than the amount which is effective in small non-human mammals subject to a correction factor based on the relative lymph node size between humans and the smaller animal (page 12, lines 32-37). It is reasonable to conclude that intradermal injection of human skin requires less antigen to activate and immune response than injection of a larger animal, encompassed by "livestock" such as a horse or a cow, or a very large domestic pet, such as a large breed dog with substantial weight (i.e. St. Bernard, Encyclopaedia Britannica 2006. Encyclopaedia Britannica Online. 19 January 2006<http://www.search.eb.com/eb/article-9064811>). The instant claims require a specific amount of tumor cells per injection. One of skill in the art would be subject to undue experimentation in order to practice the claimed method for the treatment of domestic pets and livestock with the specified amount of tumor cells because it would be expected the induction of an effective immune response would require a larger number of tumor cells.

8. Claims 21, 22, 24, 32, 33, 35, 38, 40, 41, 51, 52 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Berd et al (Cancer Research, 1986, Vol. 46, pp. 2572-2577).

Claim 21 is drawn in part to a method for inducing an anti-tumor response in a mammalian patient suffering from a tumor comprising administering on the first day of treatment a composition comprising from about 2×10^5 to about 2.5×10^6 autologous tumor cells free of adjuvant; administration of a immunomodulatory agent on day 4 to day seven of the treatment; and administration of at least one additional composition comprising autologous tumor cells. Claims 22 and 24, are dependent on claim 21 and specify that the immunomodulatory compound is cyclophosphamide, and the adjuvant is BCG, . Claims 32 and 33 specify that the tumor cells are melanoma. Claim 35 specifies that the tumor cell is rendered incapable of growth or

multiplication in vivo. Claim 38 embodies the method of claim 21 wherein the adjuvant is selected from a group including BCG. Claim 40 embodies the method of claim 21 wherein the immunomodulatory agent is administered 5 to 7 days after the initiation of the treatment. Claim 41 is dependent on claim 21 and specifies that the patient is human.

Claim 51 is drawn in part to a method for inducing an anti-tumor response in a mammalian patient suffering from a tumor comprising administering on the first day of treatment a composition comprising from about 2 X 10^5 to about 2.5 X 10^6 autologous tumor cells free of adjuvant; administration of a immunomodulatory agent on day 4 to day seven of the treatment; and administration of at least one additional composition comprising autologous tumor cells. Claim 52 specifies that the tumor of claim 52 is melanoma. Claim 54 embodies the method of claim 51 wherein the adjuvant is selected from a group including BCG.

Berd et al disclose a method of inducing an immune response to melanoma comprising administering to a human patient 1 X 10^6 autologous melanoma cells free from any adjuvant as a DTH "skin test" (page 2573, Table 3 and second column third line of "DTH Reactions") which meets the specific limitation of from about 2 X 10^5 to about 2.5 X 10^6 autologous tumor cells. Berd et al disclose that five to seven days after the skin test, cyclophosphamide was administered (Table 3) followed three days later by the vaccine comprising 10 X 10^6 autologous melanoma cells and the adjuvant BCG (page 2573, second column, third full paragraph). Berd et al disclose that the tumor cells were irradiated to a dose of 2500R (page 2573, second column, line 9), thus fulfilling the specific embodiment of claim 35.

9. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330.(CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

10. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 21-24 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 21-24 of copending Application No. 11/015,769. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

12. All other rejections and objections as maintained or set forth in the previous Office action are withdrawn.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.
1/19/2006

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PRIMARY EX...